

510(k) Summary of Safety and Effectiveness

SUBMITTER: Surgical Devices, a global business unit
of Tyco Healthcare Group LP (d/b/a Covidien)
60 Middletown Avenue NOV 22 2010
North Haven, CT 06473
Tel. No.: (203) 492-5352

CONTACT PERSON: Frank Gianelli
Senior Associate, Regulatory Affairs

DATE PREPARED: November 2, 2010

TRADE/PROPRIETARY NAME: Endo GIA™ Stapler

COMMON/USUAL NAME: Surgical Stapler with Implantable Staples

CLASSIFICATION NAME: Staples, Implantable

PREDICATE DEVICE(S): Endo GIA™ Stapler (K083519, K093410, K101444, K080898)

DEVICE DESCRIPTION: This 510(k) shall describe a new Reload cartridge with Tri-Staple™ technology for use with the currently marketed Endo GIA™ Stapler. The new Duet TRS™ Reload with Tri-Staple™ Technology bears the identical design characteristics as the Endo GIA™ Reloads with Tri-Staple™ Technology described in predicate submissions K083519 and K090419 with the exception that the Reloads have pre-attached staple line reinforcement material which is a synthetic absorbable film prepared from synthetic polyester composed of glycolide, dioxanone, and trimethylene carbonate. The staple line reinforcement material is supplied on each Reload undyed (natural) and is secured to the anvil and cartridge with BIOSYN™ synthetic absorbable suture.

Studies indicate that the staple line reinforcement material can be expected to retain measurable mechanical strength through 14 days and absorption should be complete between 90 and 110 days.

The Endo GIA™ Duet TRS™ Reload with Tri-Staple™ Technology when used with the Endo GIA™ Stapler places two, triple-staggered rows of titanium staples and simultaneously divides the tissue between the two, triple-staggered rows.

INTENDED USE: The Endo GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Note: The Endo GIA™ Duet TRS™ Reload with Tri-Staple™ Technology is intended for use with the Endo GIA™ Stapler and does not carry a separate indication from the stapling device.

**TECHNOLOGICAL
CHARACTERISTICS:**

Endo GIA™ Duet TRS™ Reloads with Tri-Staple™ Technology are substantially equivalent to the predicate devices with regard to the stapling and staple line reinforcement technologies.

Duet TRS™ Reloads with Tri-Staple™ Technology place two sets of triple-staggered rows of titanium staples along with two layers of absorbable tissue reinforcement material (one layer on cartridge side and one layer on anvil side) and simultaneously divide the tissue and tissue reinforcement material between the two sets of triple-staggered rows. These Reloads have a stepped cartridge configuration whereby for each set of triple-staggered rows, the staples in the outer row are a taller height than the staples in the middle row which in turn are a taller height than the staples in the inner row closest to the cut line. The size of the staples is determined by the selection of the appropriate single use Reload.

MATERIALS:

All components of the Endo GIA™ Duet TRS™ Reload with Tri-Staple™ Technology are comprised of materials that are in accordance with ISO Standard 10993-1.

PERFORMANCE DATA:

Bench and *in vivo* performance evaluations were conducted to demonstrate that the Endo GIA™ Duet TRS™ Reload with Tri-Staple™ Technology when used with the Endo GIA™ Stapler is safe and effective and performs as intended.

The, bench tests performed evaluated firing force, staple line pull apart strength and staple formation. The *in vivo* tests performed evaluated staple formation, hemostasis, burst strength and lung air leak.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Covidien
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

NOV 22 2010

Re: K103263

Trade/Device Name: Endo GIA™ Single Use Duet TRS™ Reload with Tri-Staple™
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: November 2, 2010
Received: November 4, 2010

Dear Mr. Gianelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

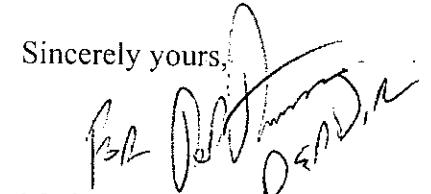
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

NOV 22 2010

510(k) Number (if known): K103263

Device Name: Endo GIA™ Single Use Duet TRS™ Reload with Tri-Staple™ Technology

Indications For Use:

The Endo GIA™ Staplers with Endo GIA™ Single Use Duet TRS™ Reloads with Tri-Staple™ Technology have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krawe for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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